

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effect of ginger powder supplement on lipid profile, insulin resistance, antioxidant status, inflammatory biomarkers and fatty liver index in overweight and obese patients with Nonalcoholic fatty liver disease (NAFLD).

#### Protocol summary

##### Summary

The purpose of this study is to assess the effect of ginger powder supplement on lipid profile, insulin resistance, antioxidant status, inflammatory biomarkers and fatty liver index in overweight and obese patients with nonalcoholic fatty liver disease (NAFLD). In this randomized, double blind, placebo controlled trial with parallel design, 46 patients suffering from NAFLD will be selected among patients referring to Gastroenterology Clinic of Imam Khomeini Hospital in Ahvaz. Participants will be randomly assigned to intervention or control group (1:1 ratio) based on the blocked randomization method. The intervention group three capsules 500 mg ginger (1500 mg per day) and the control group will use placebo for 12 weeks. Inclusion criteria include Patients aged between 20 to 70 years who will be diagnosed with NAFLD by ultrasonography scan and increased levels of liver enzymes; and have a Body Mass Index (BMI) greater than 24.9 and lower than 35. Exclusion criteria for the study will be alcohol consumption; pregnant and lactating women; any forms of hepatic or metabolic disease except NAFLD; taking hepatotoxic drugs; using nutrition supplements and have any history of gastric bypass or intestine surgery. At the beginning and end of the study different variables of the study include blood levels of lipid profile, inflammatory and oxidative stress biomarkers, insulin resistance and liver enzymes will be measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016042827652N1**

Registration date: **2016-05-04, 1395/02/15**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-04, 1395/02/15

##### Registrant information

###### Name

Roya Rafie

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3333 3050

###### Email address

rafie.r@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2016-04-29, 1395/02/10

##### Expected recruitment end date

2016-05-30, 1395/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of ginger powder supplement on lipid profile, insulin resistance, antioxidant status, inflammatory biomarkers and fatty liver index in overweight and obese patients with Nonalcoholic fatty liver disease (NAFLD).

**Public title**

Effect of ginger powder supplement on nonalcoholic fatty liver disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Men or women aged between 20 to 70 years old who will be diagnosed with NAFLD by ultrasonography scan (with steatosis score equal or greater than 1) and increased levels of liver enzymes (serum levels of alanine aminotransferase and aspartate aminotransferase more than 40 U/L); and Body Mass Index (BMI) of them is greater than 24.9 and lower than 35. Exclusion criteria: Alcohol consumption; Pregnant and lactating women; Any known forms of hepatic or metabolic disease except NAFLD, such as hereditary hemochromatosis, Wilson's disease, cirrosis, diabetes and other metabolic disease; Any history of gastric bypass or intestine surgery; Taking hepatotoxic drugs such as calcium channel blocker, methotrexate, amiodarone, chloroquine and anti inflammatory drugs; Using nutrition supplements; Hormone Therapy; and Patients with a history of hypothyroidism, Cushing's syndrome, renal failure, and kidney stones.

**Age**

From **20 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The Ethics Committee of Ahvaz Jundishapur University of Medical Science

**Street address**

The Ethics Committee, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, University City, Golestan blvd.

**City**

Ahvaz

**Postal code****Approval date**

2016-04-16, 1395/01/28

**Ethics committee reference number**

IR.AJUMS.REC.1395.73

**Health conditions studied****1****Description of health condition studied**

Nonalcoholic Fatty Liver Disease

**ICD-10 code**

K76.0

**ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

**Primary outcomes****1****Description**

Liver steatosis index

**Timepoint**

Before and after intervention

**Method of measurement**

Sonography

**2****Description**

Insulin Resistance (IR)

**Timepoint**

Before and after intervention

**Method of measurement**

Based on HOMA IR equation

**3****Description**

Liver enzymes (ALT, AST, ALP, GGT)

**Timepoint**

Before and after intervention

**Method of measurement**

Microgram/ml - laboratory kit

**4****Description**

Tumor necrosis factor alpha (TNF alpha)

**Timepoint**

Before and after intervention

**Method of measurement**

ELISA

**5****Description**

Serum Total Anti Oxidant Capacity (TAOC)

**Timepoint**

Before and after intervention

**Method of measurement**

ELISA

**6**

**Description**

High sensitive C reactive protein

**Timepoint**

Before and after intervention

**Method of measurement**

ELISA

**7**

**Description**

Fetuin A

**Timepoint**

Before and after intervention

**Method of measurement**

ELISA

**8**

**Description**

Lipid profile (TG, LDL, HDL, Total cholesterol)

**Timepoint**

Before and after intervention

**Method of measurement**

laboratory kit

**9**

**Description**

Insulin

**Timepoint**

Before and after intervention

**Method of measurement**

ELISA

**10**

**Description**

Fasting Blood Sugar (FBS)

**Timepoint**

Before and after intervention

**Method of measurement**

Colorimetric enzymatic method

**Secondary outcomes**

**1**

**Description**

Waist to hip ratio

**Timepoint**

Before and after intervention

**Method of measurement**

Non-stretchable tape without any pressure

**2**

**Description**

Body Mass Index (BMI)

**Timepoint**

Before and after intervention

**Method of measurement**

Weight (kilograms) divided by the square of height (meters)

**3**

**Description**

Systolic and diastolic blood pressure

**Timepoint**

Before and after intervention

**Method of measurement**

By mercury sphygmomanometer

**4**

**Description**

fatty liver index

**Timepoint**

Before and after intervention

**Method of measurement**

Based on the equation

**Intervention groups**

**1**

**Description**

intervention group:Three ginger capsules 500 mg daily for 12 week

**Category**

Treatment - Drugs

**2**

**Description**

The placebo group:Three placebo daily for 12 weeks

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Gastroenterology Outpatient Clinic affiliated to Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Eskandar Hajiani

**Street address**

Azadegan Ave., Department of Gastroenterology, Imam Khomeini Hospital

**City**

Ahvaz

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr Nader Saki, Deputy of research development

**Street address**

Golestan Ave., Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Roya rafie

**Position**

MSc student of Nutrition

**Other areas of specialty/work****Street address**

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### Person responsible for scientific inquiries

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**Full name of responsible person**

Seyyed ahmad hosseini

**Position**

PhD of Clinical Biochemistry

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### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*